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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,085	01/12/2001	Jaap Goudsmit	9250-28CT	3169
20792	7590	05/17/2006	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC			TUNG, JOYCE	
PO BOX 37428			ART UNIT	
RALEIGH, NC 27627			PAPER NUMBER	
			1637	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/760,085	Applicant(s) GOUDSMIT ET AL.	
	Examiner Joyce Tung	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-21, 28-31, 39-41, 43 and 45-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-21, 28-31, 39-41, 43 and 45-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The applicant's response filed 2/28/06 to the Office action has been entered. Claims 16-21, 28-31, 39-41, 43 and 45-58 are pending.

1. The objection of claim 43 is withdrawn because of the amendment.
2. Claims 16-21, 28-31, 39-41 and 43 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bastian et al. (WO 95/21849 (US 6,180,778 used herein as translation)).

Bastian et al. disclose a method of separating nucleic acid mixture into their double stranded and single stranded fraction. All nucleic acids are simultaneously adsorbed in a mineral substrate, then separated by fractional elution into double stranded and single stranded nucleic acids, or double stranded and single stranded nucleic acid of a sample are selectively adsorbed in a mineral substrate (See the Abstract). The double stranded nucleic acid predominantly binds to the first mineral support and after optionally performed washing steps, can be eluted under conditions for low ionic strength or with water (See column 3, lines 23-28). The non-adsorbed single-stranded nucleic acid collected are subsequently adjusted and can be adsorbed to a second mineral support and become eluted under conditions of low ionic strength or with water (column 3, lines 30-36). The treatment condition contains a chaotropic substance (See column 4, lines 12-16). The mineral support consists of porous or non-porous metal oxides, silica gel or glass (See column 6, lines 6-21). The particle size is 0.1 μm to 1000 μm (See column 6, lines 6-12). For binding double stranded nucleic acid to mineral supports, the solution contains quaternary ammonium thiocyanate with concentration 1 to 8 M and EDTA with the concentration from 5 mM to 200mM (See column 6, lines 49-58). Centrifuge is involved for pelletizing the silica material (See column 8, lines 53-54). Magnesium chloride, in concentration of from 0.1 to 10M may also

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be in combination for lysing or binding the sources containing nucleic acids (See column 5, lines 61-67 and column 15, claims 11-14). The complexes comprise alkaline earth metal ions bound to EDTA (See column 16, claim 22). Since the language “consisting essentially of” is considered to be open language, and in the specification, there is no clearly indication that alcohol is not allowed in the purification procedure, the teachings of Bastian et al. anticipate the limitations of claims 16-21, 28-31, 39-41 and 43.

For the purpose of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are “consisting essentially of” will be constructed as equivalent to “comprising”. See e.g. PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 (“PPG could have defined the scope of the phrase consisting essentially of for purpose of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.”).

If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicants invention. In re De lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA1964). See also ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

Accordingly, for the purposes of prior art, the claim limitation “consisting essentially of” is read as comprising and does not exclude the use of alcohol.

The response filed 2/28/06 argues that based upon the discussion of Bastian et al., in the method of Bastian, the percentage of binding single stranded RNA or double stranded DNA on a

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mineral support can be varied by altering the concentration of alcohol and thus the presence of alcohol in reagent used for binding nucleic acid materially affects the basic characteristics of the method of binding nucleic acid as proposed by Bastian et al. and therefore would affect the functional capability of the claimed liquid to facilitate binding of nucleic acid to a solid phase and thus the phrase “consisting essentially of” as used in the claims is technically distinct in its meaning that the second liquid employed in the method of the instant invention has the basic and novel characteristics of consisting essentially of material selected from the group as recited in claim 16. However, there is no evidence in the response showing the characteristics of the instant method for separating single stranded nucleic acid from double stranded nucleic acid without or with using alcohol. Moreover, for the purposes of prior art, the claim limitation “consisting essentially of” is read as comprising and does not exclude the use of alcohol. Thus, the rejection is maintained.

NEW GROUNDS REJECTIONS NECESSITATED BY THE AMENDMENT

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 45-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although the limitations do not need to be recited verbatim in the specification, the limitations need to be supported in the specification to the degree of indicating possession. The newly added ~~concept in the~~ claim language “in the absence of

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material containing alcohol groups” is not explicitly recited in the specification nor supported to the degree of indicating possession. Thus, it constitutes ~~the~~ new matter.

The response argues that it is not necessary that the application describes the claim limitations exactly ... but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that applicants invented processes include those limitations. However, according to MPEP §2163.04, entitled “Negative Limitation”, any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Thus, the rejection is maintained.

SUMMARY

5. No claims are allowable.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung J.T
May 5, 2006


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
5/15/06